K011318

OCT 25 2001

510K Summary Information

Substantial Equivalence Summary for the
Venodyne Advantage Plus Compression System

In accordance with CFR Part 870.5800 this summary is submitted by:

Thomas B.Bonner, Jr.
V.P. Regulatory Affairs/Quality Assurance
Microtek Medical, Inc.
512 Lehmberg Road
Columbus, Mississippi 39702

NAME OF THE DEVICE:

Classification Name:	Compressible Limb Sleeve
Product Code:	JOW
Common or Usual Name:	Compressible Limb Sleeve Device
Proprietary Name:	Venodyne Advantage Plus Compression System

STATEMENT OF SUBSTANTIAL EQUIVALENCE:

The Venodyne Advantage Plus Compression System is substantially equivalent to the following devices:

Venodyne Advantage Model 610 (510(k) Number: K001802) in that the basis of operation of both devices is the inflation of single chamber leg garments, which are placed on a patient's lower limbs. Inflation of the sleeve is accomplished using air, and an inflation/deflation cycle of a predetermined interval. Both systems are electrically powered and connect to the inflatable garments via air tubing.

The Venodyne Advantage Plus Compression System is substantially equivalent in function, operating parameters, and indications of use to the commercially available Venodyne Advantage Model 610 (510(k) Number: K001802) The only changes made were to the compressor and pneumatics. The compressor utilized is slightly larger to accommodate the higher pressure required for the foot compression portion of this device. Pneumatic air handling was changed to accommodate the additional function of the device. Basic circuitry, housing, display and mechanics remain unchanged as well as inflation/deflation timing cycles and preset pressures remain unchanged from the predicate device.

Novamedix LTD. AV Impulse Model 6060 (510(k) Number: K964425) in that the basis of operation of both devices is the rapid inflation of a single bladder garment placed on a patients foot. Inflation of the sleeve is accomplished using air, and an inflation/deflation cycle of a predetermined interval. Both systems are electrically powered and connect to the inflatable garments via air tubing.

The Venodyne Advantage Plus Compression System is substantially equivalent in function, operating parameters, and indications of use to the commercially available **Novamedix LTD. AV Impulse Model 6060** (510(k) Number: K964425). Inflation/deflation timing cycles and preset pressures are the same as the predicate device.

DESCRIPTION OF THE DEVICE

The Venodyne Advantage Plus Compression System is a microprocessor controlled pneumatic pump that inflates and deflates either a set of single chamber leg garments, which are placed on a patient's lower limbs or a set of single chamber foot sleeves. During power-up the system will determine which type of compression garment (either leg or foot) is attached and sets the system parameters accordingly. During the inflation cycle, the inflatable garments compress the limb and the veins contained within to a preset pressure. This assists in propelling the blood from the lower limbs toward the heart. During the deflation cycle, the veins are allowed to refill with blood. The cycle is repeated intermittently.

INDICATIONS FOR USE

The Venodyne Advantage Plus Compression System is designed to compress the lower limbs aiding the blood flow back toward the heart to help prevent DVT (Deep Vein Thrombosis) in patients at risk.

TECHNOLOGICAL CHARACTERISTICS

The Venodyne Advantage Plus Compression System has the same performance characteristics as the predicate devices. The inflation/deflation and preset pressure parameters remain exactly the same.

The pneumatic control circuitry is a microprocessor-controlled system. This allows for more flexibility in user-error detection and system status reporting to the end-user. Safety redundancy is built into the system in the form of both software and hardware components. The system will be housed in a molded plastic case and as a result is smaller as well as lighter than the predicate systems. Power is supplied via 110 VAC line current.

PERFORMANCE DATA

The Venodyne Advantage Plus Compression System performance characteristics are based on the **Venodyne Model 510** (510(k) Number: K930526) and the **Novamedix LTD. AV Impulse Model 6060** (510(k) Number: K964425). The Advantage Plus system has the same inflation/deflation cycles and preset pressures as the predicate devices.

Non-clinical validation of the Venodyne Advantage Plus Compression System showed that the inflation cycle time for the leg garments to be 12 seconds (same as predicate device), deflation cycle time to be 48 seconds (same as predicate device) and the target pressure to be 45 mmHg (same as predicate device).

Non-clinical validation of the Venodyne Advantage Plus Compression System showed that the inflation cycle time for the foot garments to be 3 seconds (same as predicate device), total cycle time to be 20 seconds (same as predicate device) and the target pressure to be 140 mmHg (same as medium pressure in predicate device).

EQUIVALENCY CONCLUSION

Results of the non-clinical bench testing of the Venodyne Advantage Plus Compression System showed that the inflation cycle time for the leg garments to be 12 seconds (same as predicate device), deflation cycle time to be 48 seconds (same as predicate device) and the target pressure to be 45 mmHg (same as predicate device). Testing of the foot garment showed that the inflation cycle time for the foot garments to be 3 seconds (same as predicate device), total cycle time to be 20 seconds (same as predicate device) and the target pressure to be 140 mmHg (same as medium pressure in predicate device). All devices supply intermittent compression to the lower limbs to promote venous return and help prevent DVT (Deep Vein Thrombosis) in patients at risk.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2001

Mr. Thomas Bonner, Jr.
Vice President
Regulatory Affairs/Quality Assurance
Microtek Medical, Inc.
512 Lehmberg Road
Columbus, MS 39702

Re: K011318
Trade Name: Venodyne DVT Advantage Plus
Regulation Number: 21 CFR 870.5800
Regulation Name: Sleeve, Limb, Compressible
Regulatory Class: Class II (two)
Product Code: JOW
Dated: August 1, 2001
Received: August 2, 2001

Dear Mr. Bonner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number	K011318
Device Name	Venodyne DVT Advantage Plus (compression system)
Indications for Use	The Venodyne DVT Advantage Plus is designed to compress the lower limbs aiding the blood flow back toward the heart to prevent DVT (Deep Vein Thrombosis) in patients at risk.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
And Neurological Devices

510(k) Number K011318

Prescription Use ✓ or Over-The-Counter Use _____
(per 21CFR 801.109)